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Please find below and/or attached an Office communication concerning this application or proceeding.

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/619,985
Filing Date: July 15, 2003
Appellant(s): STARKEY, THOMAS DAVID

I.C. Waddey, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the "Order Returning Undocketed Appeal to Examiner", mailed May 25, 2006, and the appeal brief filed August 08,2005 appealing the Office action mailed February 03, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,731,076	Noon et al	3-1988
5,139,517	Corral	8-1992
2002/0169360	Taylor et al	11-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 9-11, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Noon et al (4,731,076).

Noon et al teaches an apparatus fully capable of being inserted into a ventricle of a heart for limiting volume including:

a. a hollow plastic sac 10 or 12 with two openings 14, 16 or 18, 20 (include valves)

b. said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.

Claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Corral (5,139,517).

Corral et al teaches an apparatus for insertion into a ventricle of a heart and limits volume including:

a. a hollow plastic sac 46 with two openings

b. said sac being soft and compliant so that it will easily fill with blood to a certain,

predetermined volume, but when the sac has reached capacity, no further filling is allowed. Said apparatus is inserted into a ventricle and the opening are connected to the annulus of the inflow and outflow valves.

Regarding claim 14, the apparatus removes the pumping pressure from the heart wall reducing stress thereon.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Claims 9-11, 18-21, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (2002/0169360).

Referring to at least 12A-14C, Taylor et al teaches a flexible sac 113, 139 for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart. The sac allows the heart to pump in a more normal fashion reducing stress on the heart wall.

Regarding at least claims 18-19, see all embodiments taught by Taylor et al.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

(10) Response to Argument

The Examiner respectfully submits that appellant failed to claim their invention and properly define over the prior art. Regarding the rejection in view of Noon et al, appellant argues, "*nowhere in the Noon reference is there a description of a bladder to be implanted within a natural human heart.*" The Examiner notes that nowhere in at least claim 1 does appellant claim a "human" heart. It is the Examiner's position that the device of Noon et al is fully capable of being inserted into the heart. Appellant misses the proper reply to this position making no argument why the device of Noon is incapable of being inserted into a ventricle. The device of Noon was designed to mimic the ventricle of a human heart in size, shape, and function (see column 2, lines 61-64) which allows it fulfill the broad functional language of being "inserted" or "for placement" in a ventricle. The Examiner notes a similar device taught by Corral (following rejection) which is placed in a human ventricle.

Appellant further argues that Noon et al fails to address that the sac will fill to a predetermined volume, and when the sac has reached capacity, no further filling is allowed. For the record, the plastic sac of Noon et al has been indicated as elements 10 and 12; said elements "generally indicates" an artificial left heart and an artificial right heart and not just the interior bladder. It is within the scope of the rejection that one of the inner and outer 22 bladders or both is used in the claim interpretation. There is absolutely no statement made by Noon et al indicating that the sacs can be filled limitlessly; the sacs must have a maximum capacity which can be interpreted as a "predetermined volume". Additionally, the sacs have been described as being flexible not elastic. The sacs of Noon et al are constructed to be flexible, made of materials

such as segment polyurethane or silicone (see column 2, line 65 through column 3, line 15); **applicant's device is made of the same materials (see applicant's specification, paragraph 44). Same materials must inherently behave the same.** Appellant states: "*the bladder of Noon might be limited in the volume of blood they receive, that limitation is as a result of the outer bladder 22*". This is believed to be self-admission by appellant that the device cannot be filled endlessly and inherently has a predetermined capacity. As stated above the outer bladder can be interpreted as a portion of the apparatus.

Additionally, predetermined volume can be interpreted as that determined by the surgeon which best fits the individual patient.

Regarding appellant's winded argument directed more specifically to claim 9 that the sac when filled to capacity would "*appear in size and shape to match the size and shape of a ventricle of an undiseased human heart*", applicant fails to recognize the teaching of Noon et al as noted above, "the left heart 10 and right heart 12 are flexible bladders of a size and shape similar to natural hearts (column 2, lines 61-63)".

Regarding claim 11, "the enlarged" heart does not even have to be "the heart" mentioned in the preamble of claim 10. The Examiner disagrees and believes a sac of Noon et al is smaller than an enlarged heart of some animal. Appellant is reminded that these are device claims not method claims.

Regarding claim 20, a sac of Noon et al is fully capable of being inserted into a chamber of a heart of some animal. This claim is recklessly broad claiming merely a sac with functional language. The Examiner further believes that a sandwich bag or sac can

be inserted into a chamber of heart in any orientation and the volume of the plastic from which it is constructed would reduce or limit the volume of blood into said chamber.

Regarding the rejection in view of Corral, appellant argues that it is the outer shell 44 that limits filling to a predetermined volume and not the sac itself. Corral describes sac 46 as "a multi-layered flexible sheet of plastic material." A flexible sac does not mean it is elastic; it inherently has a predetermined volume. The sac must have been manufactured to a predetermined volume or determined by the surgeon; Corral makes no statement that any size or volume would work. Applicant is reminded of their use of the transistionary phrase "including" (or similar thereto) wherein the body of the claim can comprise additional structures. Appellant argues "*the structure of the sac of Applicant's invention limits the filling not a second liner*" which is not commensurate with the scope of the claims.

Appellant's argument regarding the device of Corral is not intended to assist with the remodeling of the enlarged heart is not commensurate with the scope of claim 1.

Appellant's argument regarding at least claim 5, wherein the method contemplates a sac as a stand alone item is not commensurate with the scope of claim 1.

Regarding at least claims 8-9, Corral teaches the outer casing approximates the heart's normal diastolic ventricular dimensions (2:42 et seq.). Therefore, it is the Examiner position that sac 46 would have a corresponding shape and would be considered to "appear generally in size... heart". If the sac did not correspond in shape, excess material not conforming would produce folds which would in turn produce blood clots.

Regarding method claims at least 14-16, 18-19, etc., Corral teaches the only claimed step of inserting a sac into a chamber of the heart and fulfills this limitation, the preamble is given no weight giving no life to the body of the claim. On the other hand, the device of Corral removes the blood pressure from the ventricle reducing stress on the wall of the chamber. The device takes over pumping and the heart can rest. A resting heart has less stress on the chamber walls and further enlargement will not occur. This reasoning additionally applies to claims 29-30.

Regarding the Taylor rejection, the Examiner notes that the device of Taylor is similar/the same of applicant's non-elected volume compensation device (VCD) shown in applicant's figure 3. Taylor's device occupies ventricular volume of an enlarged heart (ventricular aneurysm, claim 31) improving heart efficiency and allowing the heart to pump a more normal volume. With increased efficiency and increasing volume output, the heart will beat slower and more relaxed meeting the blood flow demand of the body reducing stress thereon. Claims 18-21 and 30-31 are believed to be generic to appellants DIVOLA (figure 1) and the VCD. Taylor describes the devices shown in 12A-14C as "intra-venticular volume displacement devices". The Examiner is dumbfounded that appellant is arguing a claim such as claim 20: *A flexible sac for insertion in a chamber of the heart, said sac limiting to a predetermined amount the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function.*

Taylor further teaches, "*the expandable member 113 may be preshaped as shown in FIG 12 to more closely approximate the appropriate ventricular geometry of a healthy hearth.*" See paragraph 0086.

Regarding claim 9, Taylor et al teaches the device may be filled with saline, water, etc; see paragraph 0086. Said device is fully capable of being filled with blood. Additionally, note the materials taught are identical to applicant's materials.

The rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over Corral (5,139,517) has been withdrawn.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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